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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/318,151	05/25/99	ZEITLIN	A CELG-0121

EXAMINER	
HENLEY III, R	

ART UNIT	PAPER NUMBER
1614	8

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DATE MAILED: 02/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/318,151	Andrew L. Zeitlin, et al.
Examiner	**Group Art Unit**
Ray Henley	1614

☒ Responsive to communication(s) filed on *Jan 16, 2001*

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *1-8* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1, 2, and 6-8* is/are rejected.

☒ Claim(s) *3-5* is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

CLAIMS 1-8 ARE PRESENTED FOR EXAMINATION

Applicants' response and terminal disclaimer filed January 16, 2001 have been received and entered into the application. In view thereof, the rejections based on obviousness-type double patenting and under 35 U.S.C. 103 over Richards or Baker patents are withdrawn.

Claims 1, 2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patrick et al., already of record, for the reasons of record as set forth in the previous Office action dated August 8, 2000 at page 3, as applied to claims 1, 2, 7 and 8. Claim 6 is now included as being rejected because even if the dosage form of the reference were injectable, i.e., a liquid, it would have still met the present requirement for the dosage form to be "suitable for oral administration".

Applicants' argument that the present application priority document predates the Patrick et al. reference has been carefully considered, but fails to persuade the Examiner of error. Patrick et al. shows a publication date of 1987 while applicants' earliest priority document shows a date in the year 1995, which does not predate the prior art.

Accordingly, the claims are deemed to be properly rejected.

However, to the skilled artisan, the determination of the optimum ingredient amounts to employ would have been a matter well within his/her purview and would have expected to be variable depending upon the physical characteristics of the patient being treated as well as the duration and severity of the condition suffered.

II Claims 1, 2, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Patrick et al. (J. Pharmacology. Exp. Ther (1997), 241(1), 152-8, applicants' listing as reference "AS") who teach the administration of d-threo methylphenidate to mice in order to assess the pharmacology thereof (see the abstract).

The difference between the above and applicants' claimed subject matter lies in that the reference fails to teach an injectable dosage form.

However, to the skilled artisan, the claimed subject matter would have been obvious because in the field of animal experimentation, especially where small animals such as mice are employed, the skilled artisan would have considered it routine to employ an parenteral dosage form so as to expedite administration of the drug to the test animal.

Double Patenting

I Claims 1-6 and 8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 7-23 and 25-30 of U.S. Patent No. 5,837,284 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the determination of the optimum dosage amounts would have been well

within the purview of the skilled artisan. Also, the present claims are directed to merely a "unit dosage" and thus would encompass the bolus dosage form of the patent .

II Claims 1-6 and 8 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 11 of copending Application No. 09/337,310. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims recite that the active agent is present in an effective amount and the determination of the optimum dosage would have been a matter well within the purview of the skilled artisan..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Accordingly, for the above reasons, the claims are deemed to be properly rejected and none of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ray Henley whose telephone number is (703) 308-4652.

RAYMOND HENLEY, III
PRIMARY EXAMINER
GROUP 1600

Henley; rjh
July 23, 2000